

REMARKS/ARGUMENTS

This paper request entry under 37 CFR 1.116 and 27 CFR 1.195 of new evidence submitted with the revised appeal brief filed August 13, 2004.

Applicants have previously provided the revised appeal brief and a separate paper explaining the grounds for submission of new evidence with the appeal brief as required by MPEP1207. Nevertheless, the Examiner has issued a new communication under 37 CFR1.192(c) alleging that new evidence was not submitted in a separate paper. In a subsequent telephone call, the Examiner acknowledged receipt of applicants' paper under 37 CFR 1.195 but alleged that the paper should have been filed under 37 CFR 1.116.

MPEP1207 provides as follows:

The entry of an amendment (which may or may not include a new affidavit, declaration or exhibit) submitted on an appeal continues to be governed by 37 CFR 1.116, and the entry of a new affidavit or other new evidence in an application on appeal is governed by 37 CFR1.195.

The above excerpt drawn a distinction between entry of amendments and entry of a new affidavit or other new evidence without an amendment in an application on appeal. The entry of an amendment is governed by 37 CFR 1.116. The entry of an affidavit or other new evidence without an amendment is governed by 37 CFR 1.195. Here, no amendment has been made. Thus, the entry of the new evidence with the appeal brief is governed by 37 CFR 1.195. Accordingly, applicants' submission of a new paper under 37 CFR 1.195 was appropriate.

Nevertheless, with a view to compromise and expedite consideration of substantive issues, applicants have titled the present submission under both 37 CFR 1.116 and 37 CFR 1.195.

Applicants have previously provided a revised brief and accompanying evidence, and no purpose is seen in repeating submission of these papers here. However, if the Examiner wants resubmission for any reason he is requested to telephone the undersigned.

The revised brief states which claims have been cancelled. The revised brief also states with respect to each issue whether the claims stand or fall together.

Applicants request reconsideration of the Examiner's decision not to enter the declaration and exhibits submitted with the revised appeal brief.

In the Notification of Non-Compliance of July 13, 2004, the Examiner states that the reason for refusing to enter the declaration and exhibits is that "no new rejections nor grounds for rejection were made by the Examiner." However, these comments apply the wrong standard for entry of a declaration or exhibit after appeal. The standard for entry of a declaration or exhibits with an appeal brief is provided by 37 CFR 1.195, which states:

Affidavits, declarations, or exhibits submitted after the case has been appealed will not be admitted without a showing of good and sufficient reason why they were not presented earlier.

Here, as will be discussed in more detail below, the exhibits and declaration address new points of argument by the Examiner in the final office action. The exhibits and declarations could not have been presented earlier because the arguments they address were not presented before the final office action by the Examiner.

Paragraphs (3)-(5) of the second Baekkeskov declaration and the associated exhibits from DiabetesMonitor.Com and the Diamyd Press Release cited in the Baekkeskov declaration were submitted to rebut the Examiner's allegation in the final office action that the phase II clinical trial described in the previous Baekkeskov declaration was conducted on patients suffering from a "related pathology of non-autoimmune origin" (final office action at p. 4, first paragraph). The Examiner had not made this allegation or anything like it previously in prosecution. The second Baekkeskov declaration and the associated references show that in fact the patients in the clinical trial suffer from Late Autoimmune Diabetes in Adults (LADA), a type of diabetes characterized by autoimmune destruction of the pancreas and generally recognized as being a form of type I diabetes. Thus, paragraphs (3)-(5) of the second Baekkeskov declaration and associated references address new argument in the final office action and could not have been submitted earlier.

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Findlay, Food and Drug Law Journal 54, 228 (1999) was submitted to rebut a further new argument of the Examiner in the final office action in which the Examiner attempts to buttress his case of nonenablement with the assertion that "even now, some 13 years post-filing, the establishment of tolerance in humans cannot be considered to be routine" (final office action at p. 4, first paragraph). In response, it is relevant to point out that a delay of 13 years between filing a patent application and clinical success is nothing unusual. As noted by Finlay, the average time between drug discovery and marketing is 14.7 years. Once again, the Examiner's argument based on the interval between filing of the application and establishing tolerance in humans was newly made in the final office action, and could not have been addressed earlier.

Paragraphs (6)-(12) of the second Baekkeskov declaration submitted with the original appeal brief, and a GenBank exhibit providing the sequence of GAD67 were provided to address a change in the Examiner's position regarding the disclosure of lower molecular weight GAD by US 5,762,937 between the penultimate and final office actions. Although applicants maintain that these paragraphs of the declaration and the GenBank exhibit addressed new argument, they have been deleted with a view to having the appeal proceed expeditiously on the merits.

The above discussion provides good and sufficient reason why the remaining exhibits and declaration were not presented earlier. Therefore, under 37 CFR 1.195, it is respectfully submitted that they should be admitted, and the appeal allowed to proceed on the merits without further delay.

Applicants authorized payment of the fee of \$165.00 on submission of the original appeal brief, so it is believed no additional fee is due for submitting the revised appeal brief. If the PTO determines otherwise, please charge the fee or credit any overpayment to deposit account 20-1430.

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If the Examiner believes a telephone conference would expedite prosecution of
this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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